UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 19, 1999

MEMORANDUM

Subject: Reregistration of **Fenitrothion**: Anticipated Residue and Tolerance Reassessment Recommendations; Chemical No. 105901; MRID Nos.: None: DP Barcode: D256054

From: Christine L. Olinger, Chemist
Reregistration Branch I
Health Effects Division (7509C)

Through: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch I
Health Effects Division (7509C)

and

Christina Swartz
Reregistration Branch I
Health Effects Division (7509C)

To: Stephanie Nguyen/Margaret Rice
Special Review and Reregistration Division (7508W)

HED has been asked to provide a revised risk assessment for the insecticide fenitrothion. While developing the dietary assessment, HED has identified a need for a revision to the previous tolerance reassessment and anticipated residue calculations.

A tolerance is currently established at 30 ppm for the combined residues of the insecticide O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate and its metabolites O,O-dimethyl O-(4-nitro-m-tolyl) phosphate and 3-methyl-4-nitrophenol, of which no more than 15 ppm is O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate or O,O-dimethyl O-(4-nitro-m-tolyl) phosphate, in wheat gluten resulting from postharvest application of the insecticide to stored wheat in Australia [40 CFR 185.2200(a)]. The HED Metabolism Committee (memo from B. Cropp-Kohlligian to The HED Metabolism Committee dated 2/24/93) has considered the available rice metabolism data

and has concluded that only fenitrothion per se needs to be regulated in wheat gluten imported from Australia. The Residue Chemistry Chapter to the Reregistration Eligibility Decision (B. Cropp-Kohlligian, 2/16/94) recommended for modifying the tolerance expression for residues of fenitrothion in wheat gluten imported from Australia to specify fenitrothion only at 15 ppm.

CONCLUSIONS AND RECOMMENDATIONS

HED recommends that the tolerance for residues of fenitrothion in wheat gluten be reassessed at 3 ppm, and that the expression be modified to include only the parent compound. If a refined dietary risk assessment is needed, then an average residue value of 1.84 ppm should be used. Additional information which could further refine our residue estimates includes the percent of crop treated in Australia, and percent of Australian wheat gluten which could be diverted for non-food purposes once it has been imported into the U.S.

DETAILED CONSIDERATIONS

Residue Data

In 1990 Sumitomo Chemical Company submitted a magnitude of residue study for residues of stored grain treated with fenitrothion, which was then processed into wheat gluten. This study was reviewed in the Update to the Fenitrothion and summarized in a memo (B. Cropp-Kohlligian, 4/1/93), which is repeated below:

> The registrant submitted data (1990; MRID 41468701) depicting residues of fenitrothion and its metabolites fenitrooxon and p-nitrocresol in or on wheat grain and in gluten (processed from treated wheat) from four tests in Australia collected 0, 45, and 90 days following application of an EC formulation (1000g/L Fenitrogard) to wheat prior to bin storage at 12 mg ai/kg of grain (ca. 1x the maximum single application rate for this type of treatment in Australia). Data were collected using GLC/FPD and HPLC/UV methods, which are adequate for data collection. The stated limits of detection were 0.02 ppm each for fenitrothion and fenitrooxon, and 0.04 ppm of p-nitrocresol. Samples were stored frozen (-18°C) for 2-132 days (wheat) and 106-132 days (wheat gluten) prior to analysis.
>
> The submitted data indicate that the combined residues of fenitrothion, fenitrooxon, and p-nitrocresol will not exceed the established food additive tolerance in wheat gluten processed from wheat which received a single application of an EC formulation at 12 mg ai/kg of grain (ca. 1x the maximum single application rate) prior to bin storage. Residues of fenitrothion in/on wheat and wheat gluten ranged from 5.3-11.7 and from 0.95-2.53, respectively. Residues of fenitrothion in wheat gluten processed from wheat grain which received a single application of an EC formulation at 12 mg ai/kg of grain prior to bin storage will not exceed the established food additive tolerance level for fenitrothion (15 ppm parent compound).

Since the maximum residue found in wheat gluten was 2.53 ppm, HED can now recommend for a reassessed tolerance of 3 ppm for residues of fenitrothion in wheat gluten. The tolerance expression should be modified to reflect the Metabolism Committee to regulate only the parent compound.

Anticipated Residues

Wheat gluten is not a specific food form in the DEEM™ software used to assess dietary risk. In the previous Agency assessment of dietary risk (S. Schaible, 3/25/93), HED first developed a relative ratio of approximating Australian wheat gluten consumption to wheat flour consumption. This ratio was entered into the Dietary Risk Evaluation System (DRES) along with a residue value for wheat gluten as an adjustment factor to obtain an estimate of the relative wheat gluten consumption. Implicit in the development of the factor is the assumption that the relative consumption of wheat gluten to wheat flour is the same for all population groups. The previous factor calculated was 0.23% (note this includes the contribution only from Australian wheat gluten; in 1992, approximately 40% of wheat gluten available for consumption was from Australia).

HED has updated this factor herein since the previous factor incorporated consumption data from a 1977-78 survey. BEAD provided an estimate of the amount of wheat gluten available for consumption as 250 million pounds (F. Hernandez, 4/28/99). HED has obtained data on the wheat flour supply in 1997 from the USDA Economic Research Service Wheat Yearbook (USDA Website); the total available for consumption (subtracting what is available for export) is 40,107 million pounds. Only preliminary data were available for 1998, so 1997 data were used. The relative ratio for wheat gluten to wheat flour is 0.62%.

BEAD has determined that 65 million pounds of wheat gluten are imported from Australia each year, according to quotas that were created in 1998. Based on that figure, the maximum amount of wheat gluten which could be treated with fenitrothion would be 26% (F. Hernandez, 4/28/99), assuming 100% crop treated in Australia.

An average residue value has been calculated from the residue data cited in MRID 41468701, which are summarized in Table 1. The average residue found is 1.84 ppm. This MRID also provided results from monitoring from a commercial gluten plant with unknown treatment history, which are summarized in Table 2.

Table 1. Residues of Fenitrothion in Wheat Gluten from Magnitude of Residue Studies Conducted in Four Australian States

Test Site	Residues Found, ppm
Millmerman	1.98, 1.90
Boggabri	0.95, 0.98
North Fremantle	1.93, 1.95
Beniwillock	2.53, 2.53
Average Residue	1.84

Table 2. Residues of Fenitrothion in Wheat Gluten from a Commercial Wheat Gluten Processing Plant (Unknown Treatment History)

Month Sample was Collected	Residues of Fenitrothion, ppm
November	0.87, 0.88
December	0.79, 0.82
January	0.30, 0.28
February	0.10, 0.09
March	0.09, 0.09
April	0.17, 0.16
Average Residue	0.38

cc:CLOlinger (RRB1), Circulate, Reg Std. File
7509C:CBRS:CLOlinger:clo:CM#2:Rm 816G:305-5406: 5/19/99
RDI: CSwartz: 5/19/99 WPhang: 5/19/99